

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S) : Shodai et al.
FOR : **CHEWABLE SOFT CAPSULES
HAVING IMPROVED ADMINISTRATION
PROPERTIES AND PROCESS FOR
PRODUCING THE SAME**
SERIAL NO. : 09/914,340
FILED : February 19, 2002
EXAMINER : Susan T. Tran
ART UNIT : 1615
CONFIRMATION NO. : 3665
ATTORNEY DOCKET NO. : YAMZ 2 00009

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In accordance with 37 C.F.R. §§ 1.56, 1.97, 1.98 and MPEP § 609, applicant(s) submit(s) the following Disclosure Statement concerning art of which the applicant(s) is (are) aware. A copy of PTO/SB/08 Form (renumbered from 1449) is enclosed.

This Information Disclosure Statement should not be construed to be an admission that any information referred to herein or submitted herewith is "prior art" or is considered to be material to patentability for this invention.

The United States Patent and Trademark Office OG Notice dated 12 October 2004 published a final rule revising 37 C.F.R. 1.98 dealing with the content of Disclosure Statements. Paragraph (a)(2) was revised to read in part, "A legible copy of:

(i) Each foreign patent; (ii) Each publication or that portion which caused it to be listed, other than U.S. patents and U.S. patent application publications unless required by the Office." Therefore, Applicant(s) has (have) not enclosed copies of the cited U.S. patents and published patent applications with this Information Disclosure Statement.

In accordance with 37 C.F.R. §1.97(g) and (h), the filing of this Information Disclosure Statement should not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

☐ Under § 1.98(a)(3), a concise explanation of relevance is required for information that is not in the English language. Accordingly, the English language documents have no further explanation.

☐ All of the cited and/or included documents were cited by the European Patent Office in a related application(s). A copy of the European Search Report is enclosed.

Consideration of the appropriate paragraph(s) indicated below is respectfully requested:

☐ **WITHIN THREE MONTHS OF FILING:** Under § 1.97(b)(1), this Information Disclosure Statement is being filed within three months of the filing date of the application (or date of entry of the national stage). Although it is believed no fee is necessary, any deficiency in fees should be handled as set forth below.

☐ **BEFORE FIRST OFFICE ACTION:** Under § 1.97(b)(3), this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits. Although it is believed no fee is necessary, any deficiency in fees should be handled as set forth below.

☒ **BEFORE FINAL ACTION, OR NOTICE OF ALLOWANCE, OR ACTION THAT CLOSES PROSECUTION/WITH STATEMENT:** Under § 1.97(c)(1), this information shall be considered if filed before the mailing date of a final action, or a Notice of Allowance or action that otherwise closes prosecution in the application if accompanied by the statement:

Under § 1.97(e)(1), the undersigned states:

☒ A. that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement; or

☐ B. that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in §1.56(c) more than three months prior to the filing of the Information Disclosure Statement.

☐ **BEFORE FINAL ACTION, OR NOTICE OF ALLOWANCE, OR ACTION**

THAT CLOSES PROSECUTION/WITH FEE: Under § 1.97(c)(2), this information shall be considered if filed before the mailing date of a final action if accompanied by a fee in the amount of \$180.00 as required by §1.17(p). Accordingly, the necessary fee accompanies this Information Disclosure Statement, as set forth below.

☐ **AFTER FINAL ACTION, OR NOTICE OF ALLOWANCE, OR ACTION**

THAT CLOSES PROSECUTION/AND ON OR BEFORE PAYMENT OF THE ISSUE FEE:

1. Under § 1.97(e)(1), the undersigned states:

☐ A. that each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the Information Disclosure Statement; or

☐ B. that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the Information Disclosure Statement; **and**

2. ☐ the fee in the amount of \$180.00 as required by §1.17(p). Accordingly, the necessary fee accompanies this Information Disclosure Statement, as set forth below.

☐ **PRIORITY CLAIM:** The enclosed PTO/SB/08 includes all patents, publications, or other information previously cited by or submitted to the Office in one or more prior applications from which the present application claims priority. These one or more prior applications are identified in the papers accompanying the filing of this application.

Any payment due for the filing of this Information Disclosure Statement is authorized to be charged to a Credit Card. **If the Credit Card is unable to be charged, please charge any and all fees or credit any overpayment to Deposit Account No. 06-0308.** If there are any additional fees required by this communication, please charge same to Deposit Account No. 06-0308.

It is respectfully requested that the attached document(s) be considered and officially cited in examination of this application.

Respectfully submitted,

FAY SHARPE LLP

April 5, 2007
Date

/s/ Richard M. Klein
Richard M. Klein, Reg. No. 33,000
1100 Superior Avenue
Seventh Floor
Cleveland, OH 44114-2579
216-861-5582

CERTIFICATE OF MAILING OR TRANSMISSION	
I hereby certify that this correspondence (and any item referred to herein as being attached or enclosed) is (are) being	
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<input checked="" type="checkbox"/>	transmitted to the USPTO by electronic transmission via EFS-Web on the date indicated below
	Signature: /s/ Lynda S. Kalemba
Date: April 5, 2007	Name: Lynda S. Kalemba

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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

Application Number	09914340
Filing Date	2002-02-19
First Named Inventor	Shodal
Art Unit	1815
Examiner Name	Tran
Attorney Docket Number	YAMZ 2 00009

U.S. PATENTS

Examiner Initial*	Cite No	Patent Number	Kind Code ¹	Issue Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Patent citation information please click the Add button.

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No	Publication Number	Kind Code ¹	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
	1					

If you wish to add additional U.S. Published Application citation information please click the Add button.

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No	Foreign Document Number ²	Country Code ²	Kind Code ⁴	Publication Date	Name of Patentee or Applicant of cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ³
	1	97/36663	WO	A2	1997-10-23	Flemington Pharmaceutical Corporation		<input type="checkbox"/>

If you wish to add additional Foreign Patent Document citation information please click the Add button

NON-PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁴

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1		<input type="checkbox"/>
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If you wish to add additional non-patent literature document citation information please click the Add button

EXAMINER SIGNATURE

Examiner Signature		Date Considered	
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

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STATEMENT BY APPLICANT**
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Filing Date	2002-02-19
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Art Unit	1615
Examiner Name	Tran
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CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

- ☒ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

- ☐ See attached certification statement.
- ☒ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.
- ☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

Signature	/s/ Richard M. Klein	Date (YYYY-MM-DD)	2007-04-05
Name/Print	Richard M. Klein	Registration Number	33,000

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 213(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.